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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,997	07/23/2003	**Peter Fuenfschilling**	100-8345E	8182

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,997	FUENFSCHILLING ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/9/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17,19,21-28,30-36,38,39 and 41-48* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17,19,21-28,30-36,38,39 and 41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 12/14/07 is acknowledged. There remain no amendments to the claims. Claims 11-17, 19, 21-28, 30-36, 38-39, and 41-48 remain pending and examined on the merits.

As stated in the previous action:

The present application has been transferred from former Examiner Shirali to the present Examiner. Claim 18 remains withdrawn. Claims 11-17, 19, 21-28, 30-36, 38-39, and 41-48 are pending and examined on the merits. It is noted that all the claims, except claim 18 (countercurrent product), are product by process. As the previous Examiner indicated, a product by process is still nevertheless a product (like the claim structure in claim 19): [E]ven though product-by-process claims are limited by and defined by the process; *determination of patentability is based on the* ***product*** *itself. The patentability of a* ***product*** *does not depend on the method of production.* If the product in the product-by-process claim is the *same as or obvious from a product* of the prior art, the claim is unpatentable even though the prior product was made by a different process" (*In re Thorpe*, 777 F2d 695,698, 227 USPQ 964,966 (Fed. Cir.1985)(emphasis added)). [Note: Should Applicant be pursuing a new method of making a known product (e.g. substantially pure to pure (99.5% or >) cyclosporins; see e.g. specification page 6), the appropriate claim format is through a method of making (rather than product or product by process), which may be pursued via a divisional or continuation out of the present application.]

Per the above, the Examiner suggests that Applicant may wish to consider filing a continuation application in the pursuit of a different method of making/producing bulk cyclosporine, along the lines of the process claims originally presented in this application (7/23/03).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 11-17, 19, 21-28, 30-36, 38-39, and 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudat et al. (US 5,256,547) is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive.

Applicant argues that it would not have been obvious to arrive at an amount of 1 kg, for the already known bulk product of cyclosporin. So in other words, Applicant is arguing that one of skill in the art wouldn't have been motivated to produce about 1 kg (or for that matter 10, or 100, or 1 million kg's) of purified cyclosporine, over the course of an entire 24 hour day, or even a week, or stretched out to a month; depending on the size of the order to be filled and/or the speed in which he & his colleagues desired to fill said bulk amount of at or over 1 kg? Applicant's arguments are simply not found persuasive. A bulk product of cyclosporin is well known. Including the obviousness that "about 1 kg" has/could have been produced by e.g. the Rudat et al. lab, over the course of some period of time. The latter of which is not claimed. But

even if it were, the speed at which a known product is produced does not impute 'novelty' or 'unobviousness' to the 'known' product. (Applicant's arguments are more aptly described as those which would be directed to process subject matter, which is not under examination). The amount element of a known product, even if not expressly taught, is merely an obvious quantity of a known product that could be produced depending on the amount desired. Amount and the time to produce said amount, are processing issues, not known product issues.

The substance of the rejection is repeated below for continuity of record.

Rudat et al. teach a bulk quantity of cyclosporin. But not expressly about 1 kg.

Rudat et al. is discussed above. Rudat et al. teach a *bulk quantity* of cyclosporin A [though less than Applicant, but still a bulk quantity] *with an impurity level of less than 0.5%* by area using HPLC (see e.g. Example 8, 100% pure cyclosporine A in a bulk quantity of 61.5g; entire document). Although Rudat et al. teaches a bulk production of cyclosporine (61.5 g), the reference does not expressly teach that one of skill in the art could naturally carry out the same process to produce e.g. greater than 1 kg of the pure cyclosporine (e.g. Applicant's claim 11). [It is noted that Applicant is claiming "substantially pure" to "pure" cyclosporine, since the claimed range is 99.5% or greater up to 100%. "Pure" equates to 100% by the United States Pharmacopoeia and supplement; while "substantially pure" does not require absolute purity of 100% (> 99.5% to 99.999% as claimed)].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce about a 1 kg or greater quantity of cyclosporine (with greater than 99.5%) in Rudat et al., because Rudat et al. advantageously teach a bulk quantity of PURE cyclosporine,

and election to produce a bulk amount of 1 g, 500 g, 1 kg, or 2 million kg's of the same is merely a matter of judicious selection by the manufacturer of the cyclosporine depending on the number of e.g. prescriptions projected to be filled for the following month, year(s) as determined by the manufacturers client requests and internal marketing and research team.

As to the product by process claims - [E]ven though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the* ***product*** *itself. The patentability of a* ***product*** *does not depend on the method of production.* If the product in the product-by-process claim is the *same as or obvious from a product* of the prior art, the claim is unpatentable even though the prior product was made by a different process" (*In re Thorpe*, 777 F2d 695,698, 227 USPQ 964,966 (Fed. Cir.1985)(emphasis added)).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Prior Art Made of Record But Not Relied Upon

Per Applicant's request, the Business Wire reference, which was previously in this section and not relied upon in the last action, but merely cited by example that it was known that bulk quantities of 1 kg or more were capable of being produced, has been transferred back to this section rather than being cited within the rejection section – as it is not necessary to show the obviousness of producing the known bulk product of cyclosporin, in an amount of "about 1 kg".

Business Wire (Business Wire, "SangStat Announces Agreement with Eli Lilly for Manufacturing of CYCLOSPORINE; SangStat Retains Worldwide Commercial Rights"; Nov. 6, 1996, http://www.findarticles. com/p/articles/mim0EIN/is_1996_Nov_6/ ai_18835470 – previously cited under Prior Art Made of Record but Not Relied Upon).

As noted previously, Business Wire, *cited merely by example that bulk manufacturing (e.g. greater than 1 kg) of cyclosporine is well known in the pharmaceutical industry*, Business Wire published an article as far back as November 1996 (e.g. which would predate Applicant's 9/11/96 priority date [what was meant here was that bulk production, as indicated in the reference, had been known years before Applicant's earliest effective filing date] detailing years of previous development by SangStat for a proprietary cyclosporine to be later produced in bulk, for which Eli Lilly was selected to do the bulk manufacturing. [Applicant like Eli Lilly, is assumed to be one of ordinary skill in the art in bulk manufacturing, and it is assumed the Lilly process can produce about 1kg or more – absent credible evidence by Applicant that one of his skilled artisans (Lilly) process actually cannot produce this quantity].

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 3/15/2008

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654